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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/753,061	01/08/2004	Johan Boelens	17601.43	2469

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EXAMINER	
ROGERS, MARTIN K	
ART UNIT	PAPER NUMBER
1747	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/753,061	BOELENS ET AL.	
	Examiner	Art Unit	
	MARTIN ROGERS	1747	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 November 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5,6,9,11,12,15,16 and 21-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3, 5, 6, 9, 11, 12, 15, 16, 21-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4, 9, 10, and 21-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson et al. (EP 1132059 already of record) in view of Gurbel et al (USP 5295959), Guinan (Pre-Grant Publication 2003/0060832), Spreigl et al. (USP 6161029), Klumb et al. (USP 6238430), Harada et al. (USP 5242451), Wiktor (USP 4886062), Blackshear Jr. et al. (USP 5308356) and optionally Tower (USP 5352199).

In regards to claims 1, 5, 15 and 23, Johnson discloses folding a balloon into a number of longitudinal pleats, either manually or by machine ([0031]), placing the balloon into a mold, and pressurizing and heating the mold ([0035] and [0036]) to create protrusions in any area where the balloon is not compressed with a phantom stent ([0040]). The phantom stent is later removed and replaced with the actual stent after the shaping operation. Although Johnson does not explicitly disclose positioning a stent defining a plurality of apertures around the balloon such that the protrusions extend through the plurality of apertures defined by the stent, it is disclosed that Johnson envisions using a multitude of currently available stents ([0020]), suggesting to one of ordinary skill in the art that any well known stent geometry for use with an inflatable balloon catheter would be suitable for the invention of Johnson. Johnson is silent as to the method used to form the balloon catheter, suggesting to one of ordinary skill in the art that any well known method for making such a balloon catheter would be suitable for the invention. In the process of Johnson, the protrusions are formed after the balloon has been attached to the catheter tubing.

The use of stents with a plurality of apertures between adjacently spaced loops in the stents are well known in the art. Evidence for this is provided by Spreigl (Figure 6: 130), Klumb (Figure 2E: 48), Harada (Figure 5b: 10), and Wiktor (Figure 6: 1). It would therefore be obvious to one of ordinary skill in the art use a stent with spaced coils (as disclosed by the cited examples) with the invention of Johnson for the benefit of these being well known stents in the art for use with a balloon catheter. Johnson discloses that any area of the balloon not compressed by the phantom stent will protrude (Figures

3 and 7). In order to achieve the position-retention advantages disclosed by Johnson ([0040]), which are achieved by molding the balloon into conformity with a phantom stent ([0041]), the combination of references will result in protrusions forming between the loops of the phantom stent during the molding step. The helical shape of the cited stents will require a wrapped phantom stent in order to achieve a spiral-shaped groove in the balloon. The shape of the cited stents will also require that the protrusions be created along the length of the balloon. It is therefore the examiner's position that these protrusions will then extend through spaces in the actual stent.

In any event, Gurbel suggests to one of ordinary skill in the art that by providing the exterior of a balloon with recesses that match the coils of a stent, the stent is held more securely during surgery and the outer profile of the catheter is made more compact and smooth (Column 3, lines 3-6). It is stated by Gurbel that these recesses are created with the use of a wrapped phantom stent during the molding step (Column 6, lines 32-36). One applying the teachings of Gurbel to the catheter molding step of the previous combination would therefore find it obvious to create recesses in the catheter balloon (as disclosed by Gurbel) with protrusions that are specifically adapted to extend through the spaces in the stent in order to securely hold the stents of the above combination as well as reduce the profile of the catheter.

Guinan discloses that one of ordinary skill would consider it functionally equivalent to form protrusions in a catheter balloon by either inflating non-compressed portions of the balloon or simply using radially-compressive force to form a profile in the balloon while the balloon is in a deflated state ([0021]) and applying heat to the balloon

([0020]). Therefore, one of ordinary skill in the art would have found it obvious to create the protrusions of the previous combination without an inflation mold by heat-setting the balloon in an uncompressed state because this is considered to be functionally equivalent to inflating the balloon during the protrusion-forming process (as disclosed by Guinan).

Blackshear discloses that one well known method of making a balloon catheter is to introduce a tube into a mold and inflate in the tube into the shape of the balloon (Column 6, lines 41-46). In order to use the product, it must inherently be removed from the mold after being formed. Therefore, one of ordinary skill would have found it obvious to mold the balloon of the above combination using the steps required by Applicant because this balloon-forming method is well known in art (as disclosed by Blackshear). The examiner notes that although Johnson discloses forming the protrusions in a "mold," this is after a cylindrical balloon has already been molded. Therefore, the protrusion forming steps occur after the molding of the cylindrical balloon (as required by the claim language).

Although Johnson discloses forming protrusions in the balloon after it has already been attached to the catheter tubing, it is the examiner's position that one of ordinary skill would appreciate that there are very limited number of possibilities for creating a balloon with a shaped catheter on the end. The balloon can either be attached to the catheter before or after the shaping step. Therefore, by virtue of the limited number of possibilities, one of ordinary skill would find it obvious to first shape the balloon and then attach it to the catheter tubing. Tower shows that it is well known in the art to first create

a shaped balloon (with an inflation step) and then afterwards attach it to catheter tubing (Column 2, lines 20-21 and Column 3, lines 2-5).

The examiner additionally notes that it is obvious to rearrange the sequence in which process steps are performed. See In re Burhans, 154 F.2d 690, 69 USPQ 330 (CCPA 1946).

In regards to claims 2 and 24, Guinan further discloses applying heat ([0020]) during the protrusion forming. Because the stents of the above combination span the length of the balloon, one of ordinary skill would find it obvious to heat the length of the balloon.

In regards to claim 3, Johnson further discloses the use of PTFE.

In regards to claims 6 and 16, Johnson further discloses that the balloon be attached to a catheter ([0032] and Figure 2: 18).

In regards to claim 9, Johnson further discloses the use of PTFE. Harada further discloses that one well known type of stent has a flat-band shape (Figure 5), therefore requiring a phantom stent that is also a flat band.

In regards to claim 12, Johnson further discloses that the balloon be attached to a catheter ([0032] and Figure 2: 18).

In regards to claim 25, it is generally well known in the art to fold balloons using the actual stent, or by hand, or by using a folding machine. These methods are known equivalents for forming a balloon.

In regards to Claim 11, the subject matter is rejected for the same reasoning presented above for claim 23.

In regards to claims 21 and 26 Harada further discloses that one well known type of stent has a flat-band shape (Figure 5), therefore requiring a phantom stent that is also a flat band.

In regards to claim 22 and 27, Spreigl further discloses a catheter with a thread-like cross-section (Figure 6) and Klumb also discloses a thread-like stent (Figure 2), therefore requiring a phantom stent in the form of a filament or thread for the process of Johnson.

In regards to claim 28, Johnson further discloses forming the protrusions into a folded balloon ([0032]-[0033]). If the balloon were attached after the process of forming the protrusions, the balloon would be folded when it was attached to the catheter tubing.

Response to Arguments

Applicant's arguments filed 11/23/2010 have been fully considered but they are not persuasive.

Applicant argues on page 7 of the remarks that Johnson discloses using heat and inflation of the balloon to form protrusions, rather than the simple compression required by the claims. The examiner notes that Guinan was cited in the rejection and shows that it is considered to be functionally equivalent to either use inflation of radial compression to form protrusions in a balloon. Applicant points out on page 8 of the remarks that Guinan does not discloses forming protrusions other than longitudinally spaced "steps" and that it is unclear from Guinan whether or not the crimped stent which forms this protrusions is removed. However, the examiner notes that Applicant appears to be arguing the references individually. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). It is the combination of references which discloses the use of a removable temporary stent to form protrusions which have the configuration required by the claims. Although Guinan discloses that the compression is created by crimping the protrusion-forming stent, the combination of references requires a wrapped protrusion-forming stent. Guinan was simply relied upon to show that a skilled artisan would appreciate that providing a radially compressive force to a balloon

for a period of time and inflating a balloon are two functionally equivalent methods for forming protrusions in a balloon.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARTIN ROGERS whose telephone number is 571-270-7002. The examiner can normally be reached on Monday through Thursday, 7:30 to 5:00, and every other Friday, 7:30 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Richard Crispino can be reached on 571-272-1226. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Martin Rogers/

/Richard Crispino/
Supervisory Patent Examiner, Art Unit 1747